Remarks

Claims 3-19, 26, 31-35, 37, and 38 are pending in the application. Claims 26 and 37 have been amended. No new matter has been added. Applicant believes these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicant respectfully submits that the claim amendments do not limit the range of any permissible equivalents.

35 U.S.C. §112 Rejection (Written Description)

Claims 3-19, 26, 31-35, and 37 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that these claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner further asserts that:

> Instant claim 37 recites medicinal agents selected from the group consisting of a pharmaceutical active, a supplemental nutrient, a beneficial agent and a combination thereof, which are further limited, in the dependent claims to various groups of pharmaceutical agents such as anti-neoplastic agents, anti-depressant, an autonomic drug etc., supplemental nutrients such as fermentable or non-fermentable dietary fiber, oligosaccharide, phytochemical, pyruvate precursor etc., and beneficial agents such as probiotic, an enzyme, a diagnostic agent etc. However, besides mentioning aspirin and sildenafil citrate, [the specification] does not describe or exemplify any specific drug or an enzyme or a phytochemical or probiotic or a diagnostic agent that could suitably be employed in the instant filter bag. Accordingly, a mere listing of a pharmaceuticals [sic] or beneficial agents by their function does not provide adequate written description as it does not concisely convey to one skilled in the art that [the] inventors, at the time of the instant was filed, was in possession of the claimed invention.

For the reasons set forth below, Applicant respectfully disagrees and submits that the subject matter of claims 3-19, 26, 31-35, and 37 is fully supported by the specification.[1]

An objective standard for determining compliance with the written description

[1] Independent claim 26 was also rejected as failing to comply with the written description requirement, but there is no basis for this rejection provided.

requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). MPEP § 2163.02.

As set forth in the MPEP, the Examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person in the art would not recognize that the written description of the invention provides support for the claims. MPEP § 2163. The Examiner has not met this burden by failing to present evidence or reasons why a person in the art would not recognize that the written description of the invention provides support for the claims. Although claim 37 is not an original claim, the element that the Examiner finds offensive was present in original claim 2. Thus, there is a strong presumption that an adequate written description of the invention as embodied in this element is present in the specification as filed. *Id.*

The Examiner's sole argument appears to be that the specification "does not describe or exemplify any specific drug or an enzyme or a phytochemical or probiotic or a diagnostic agent that could suitably be employed in the instant filter bag" and that "a mere listing of a pharmaceuticals or beneficial agents by their function does not provide adequate written description support." But the MPEP states that each claim should be evaluated to determine if sufficient structure, acts, or functions are recited to make clear the scope and meaning of the

claim. *Id.* The absence of definitions or details for well established terms or procedures should not be the basis of a rejection for lack of adequate written description. *Id.*

Furthermore, Applicant respectfully submits that contrary to the Examiner's assertion that the agents are listed by their function, the agents are listed using generic classifications principally setting forth their therapeutic properties. Each of the generic classifications include categories of agents that can be suitably employed on the instant filter bag and are well known to those of ordinary skill in the art. For example, the generic classification of pharmaceutical actives includes cancer reducing agents, mood elevating drugs, depressant drugs, anti-diabetic drugs, anti-ulcer drugs, gastrointestinal drugs, infertility and fertility drugs, hormones, erectile dysfunction agents, anti-inflammatory drugs, blood formation and coagulation drugs, anti-coagulent drugs, anti-platelet agents, ace inhibitors, cardiovascular conditioning drugs, cholesterol reducing agents, lipid reducing agents, antihistamine drugs, anti-infective agents, antivirals and urinary tract anti-infectives, autonomic drugs and central nervous system agents, smooth muscle relaxants, antitussive agents, and expectorant and mucolytic agents all of which are categories of agents that are well know to persons of ordinary skill in the art.

In support of this, Applicant submits the results of a GOOGLE search for various categories. A chemotherapy agent search yielded seven-thousand results (a copy of the first page of the search is attached). Additional searches were performed for other categories and are also enclosed for the Examiner's review. These search results show that the terms used in the specification and claims are well-known and commonly used by those of ordinary skill in the art. Additionally, there are a number of reference guides used by those skilled in the art that provide specific agents included within a category. For Example, the PDR (Physicians Desk Reference) provides information on prescription drugs, over the counter drugs, herbal medicines, and nutritional supplements.

Accordingly, Applicant submits the claims use descriptive means, namely, generic classifications, to concisely convey to one skilled in the art that Applicant, at the time the instant application was filed, was in possession of the claimed inventions.

Furthermore, contrary to the Examiner's assertion, the specification does set forth specific medicinal agents other than the two identified in the Office Action. Examples include:

antihistamine drugs such as H_2 blockers; minerals such as traces of selenium, chromium, molybdenum, zinc, and copper, electrolytes, gold compounds; oligosaccharides such as fructo-oligosaccharides, pyruvate precursors in the form of pyruvamide, or pyruvyl-amino acids, such as, pyruvyl-glycine, pyruvyl-alanine, pyruvyl-leucine, pyruvyl-valine, pyruvyl-sarcosamine and their amides. (Page 6, lns. 14-24).

The MPEP provisions addressing adequate written description deal primarily with two different situations. In one case, the specification only discloses a species and the claim recites the genus. In the other case, the specification discloses only the genus and the claim recites the species. Neither applies here. Rather, both the claims and the specification are equal in breadth and teach that medicament used for coating the filter bag material is present in a therapeutically effective amount and may include pharmaceutical actives, supplemental nutrients, genetically derived materials, other beneficial agents, or combinations thereof. (Page 6, lns. 6-8). For each of the above groups exemplary agents are provided. For example, pharmaceutical actives suitable for use in the coating include, but are not limited to, aspirin, cancer reducing agents, such as chemotherapy agents and anti-neoplastic agents, mood elevating drugs, depressant drugs, anti-diabetic drugs, anti-ulcer drugs, gastrointestinal drugs, such as antacids, infertility and fertility drugs, hormones, erectile dysfunction agents such as sildenafil citrate, anti-inflammatory drugs, blood formation and coagulation drugs, anti-coagulent drugs, anti-platelet agents, ace inhibitors, cardiovascular conditioning drugs, cholesterol reducing agents, lipid reducing agents, antihistamine drugs such as H_2 blockers, anti-infective agents, such as antibiotics, antivirals and urinary tract anti-infectives, autonomic drugs and central nervous system agents such as adrenergic agents and skeletal muscle relaxants, smooth muscle relaxants, antitussive agents, and expectorant and mucolytic agents. (Page 6, lns. 14-24).

In light of the foregoing, reconsideration and withdrawal of the written description requirement rejection is respectfully requested.

35 U.S.C. §112 Rejection (Enablement)

Claims 3-19, 26, 31-35 and 37 were also rejected under 35 U.S.C. 112, first paragraph as not being enabled. For the reasons set forth below, Applicant respectfully disagrees and submits

that claims 3-19, 26, 31-35 and 37 are enabled by the specification.

Initially, Applicant notes the Examiner states the specification is enabling for a filter bag coated with aspirin or sildenafil citrate. However, as noted above, the specification discloses a number of other specific agents for coating a filter bag, namely; antihistamine drugs such as H_2 blockers; vitamins and minerals such as traces of selenium, chromium, molybdenum, zinc, and copper, electrolytes, gold compounds; oligosaccharides such as fructo-oligosaccharides, pyruvate precursors in the form of pyruvamide, or pyruvyl-amino acids, such as, pyruvyl-glycine, pyruvyl-alanine, pyruvyl-leucine, pyruvyl-valine, pyruvyl-sarcosamine and their amides. (Page 6, lns. 14-24). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPG 18, 24 (CCPA 1970), MPEP § 2164.01(b). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524. 1533, 3 USPQ2d 1737, 1743 (Fed Cir). MPEP § 2164.01(b).

Applicant submits that the method of making and using a filter bag coated with any of the above identified specific examples bears a reasonable correlation to the method of making and using a therapeutically effective amount of at least one medicinal agent on a filter bag. For example, claim 37 recites that the medicinal agent is selected from the group consisting of pharmaceutical active (aspirin), supplemental nutrient (eucalyptus), a beneficial agent (vitamin) and a combination thereof. For each one of these groups, the specification sets forth at least one specific example (identified in the parentheticals). Accordingly, Applicant respectfully submits that claims 3-19, 26, 31-35 and 37 meet the enabling requirement of 35 U.S.C. 112, first paragraph, and request reconsideration and withdrawal of the 35 U.S.C. 112 rejection.

Additionally, the Examiner asserts that the:

> instant specification provides no guidance as to how to prepare the medicament such that it is incorporated in the bag materials, i.e., as a powder or solubilized and applied [as] a liquid coating etc. Further it is not mentioned if all of the materials claimed i.e., drugs or nutrients or other beneficial agents, are soluble upon contact with liquid, or any mechanism as to how the medicaments claimed are released.

The Examiner further asserts that:

> In the absence of any guidance from the instant specification, one of an ordinary skill in the art would have to perform undue experimentation in order to identify or choose the right compound that belongs to the claimed categories, chose [sic] the amount to be incorporated, prepare an appropriate liquid or solid or a powder or other suitable form of the compound so as to apply to the filter bag and finally in the process of application of the medicament i.e., mix with the porous sheet material before forming the sheet, apply the sheet material by affixing or spraying the medicament, sprinkle the medicament or dip the paper into medicament solution etc. Thus further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation. *United States v. Telectronics, Inc.*, 857 F.2d 778, 784, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), MPEP § 2164.01. A patent need not teach, and preferably omits what is well known in the art. *In re Buchner*, 929 F.2d 600, 661, 18 USPQ2d 1331, 1332 (Fed. Cir 1991), MPEP § 2164.01. The fact the experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriesr*, 221, USPQ 1165, 1174 (Int'l Trade Comm'n 1983), MPEP § 2164.01. For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. MPEP § 2164.01(c).

Applicant notes that the preparation of medicinal agents in powder or liquid forms is well known to one skilled in the art and that such information could be obtained without undue experimentation. For example, as noted above, there are reference guides, such as the PDR, which provide information on medicinal agents which one skilled in the art may use without undue experimentation. As such, the specification is not required to teach methods for preparing the medicinal agents and it is preferable that the specification omits such teachings.

Furthermore, the specification does provide methods for applying the medicinal agent to the porous material. As illustrated in FIG. 2, the medicament 10 is sandwiched in between a

lower filter bag material layer 30 and an upper filter bag material layer 40. (Page 7, lns. 10-11). In one embodiment, a drug releasing element, such as gelatin, may be impregnated on the surface of the filter bag material after applying the medicament, thus sandwiching the medicament between the gelatin layer and the filter bag material. (Page 7, lns. 24-26).

The specification also provides teaching as to release of the medicinal agent. Specifically, the medicament solubilizes when in contact with liquid and is dispersed in the proper dosage amount into the liquid for oral consumption. (Page 5, lns. 29-31). Additionally, upon immersion in a liquid 70, the gelatin layer 40 breaks down into gelatin particles 40a, which dissolve into the liquid 70, and the medicament 10 is released into the liquid 70, as depicted in FIG. 4. (Page 7, lns. 29-32).

Applicant respectfully submits that it is not necessary to set forth the solubility limits of every medicinal agent in a particular liquid at a given temperature range. Rather, the solubility of these medicinal agents is well known to one skilled in the art such that such information could be obtained without undue experimentation.

Accordingly, Applicant submits that the specification teaches the release of the medicinal agents into the liquid, where the medicinal agent solubilizes when in contact with liquid, or, in the instant of the gelatin coated filter bag, the gelatin dissolves into the liquid releasing the medicinal agent.

In light of the foregoing, Applicant submits that claims 3-19, 26, 31-35 and 37 are enabled by the specification. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 112 rejection.

35 U.S.C. §102(b) Rejection Claims 6-8, 18, 19, 26, 34, 35 and 37

Claims 6-8, 18, 19, 26, 34, 35 and 37 were rejected under 35 U.S.C. 102(b) are being anticipated by GB 1603414 ("GB"). For the reasons set forth below, Applicant respectfully submits that the rejected claims are not anticipated by GB.

As noted by the Examiner, GB discloses a method for producing tea bags from which infusions having improved colour can be derived. (Page 1, lns. 31-32). Teas brewed in water with high temporary hardness often have an undersirable grey-brown colour. (Page 1, lns. 12-

13). It is known that citric acid improves the colour of the tea liquor obtained on infusion. (Page 1, lns. 16-17).

The improved colour of the tea liquor on infusion is obtained if the tea bag is made from water-pervious sheet material having edible acidic material incorporated thercin. (Page 1, lns. 34-36). The acidic material being selected from the following: citric acid, malic acid, glutaric acid, tartaric acid, succinic acid, monosodium hydrosulphate, and buffering mixtures of any of these acidic material with water-soluble salts of the same acidic materials. (Page 1, lns. 45-48).

As such, GB discloses a tea bag having an edible acidic material incorporated thereon for improving the color of the tea infusions for teas brewed in water with high temporary hardness. The only disclosed improvement by the acidic material is an improved color in the tea infusion. The GB patent notes flavor in determining appropriate acidic material, specifically in the table in Examples 1-6 (Page 3, lns. 1-8) and on page 4, lines 7. However, GB does not disclose that the acidic material improves the flavor of the tea infusion. Furthermore, GB does not disclose that the acidic material is a therapeutically effective amount of a medicinal agent which produces a therapeutic response upon oral administration.

In contrast, the present invention is directed to a coated filter bag for oral administration of medicament. The present invention advantageously allows for a palatable, easy method for administering medicaments in proper dosage amounts for those who prefer not to or are not able to swallow a pill. (Page 5, ln. 31 – page 6, ln. 2). The medicament used for coating the filter bag material is present in a therapeutically effective amount and may include pharmaceutical actives, supplemental nutrients, genetically derived material, other beneficial agent, or combinations thereof. (Page 6, lns. 6-8). As used herein, "therapeutically effective amount" is an amount that produces the desired therapeutic response upon oral administration. (Page 6, lns. 9-11).

Claims 26 and 37 now recite a filter bag for oral administration of medicament that includes at least one sheet of porous material forming a sealed bag. The filter bag includes a therapeutically effective amount of at least one medicinal agent incorporated into the porous material. The therapeutically effective amount of the at least one medicinal agent produces a therapeutic response upon oral administration.

Applicant submits that each and every element of the invention as recited in claims 26

and 37 are not disclosed in GB. As noted above, GB is directed towards a tea bag having an edible acidic material incorporated thereon. The acidic material is disclosed only as improving the color of the tea infusions for teas brewed in water with high temporary hardness. GB does not disclose a medicament applied to the material that makes the tea bag. Specifically, GB does not teach or suggest a therapeutically effective amount of at least one medicinal agent which produces a therapeutic response upon oral administration.

In light of the foregoing, amended independent claims 26 and 37 are respectfully submitted to be patentable over GB. As claims 6-8, 18, 19, and 37 depend from amended claim 37 and claims 34 and 35 depend from amended claim 26 and necessarily include all the elements of their respective base claims, Applicant respectfully submits that these claims are also allowable over the cited reference at least for the same reasons.

35 U.S.C. §103 Rejections

Claims 3-5, 9, and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over a combination of JP 09108111 (JP '111) and GB or unpatentable over GB and JP '111 in view of CN 1104036 (CN).

Claims 10-17 and 31-33 were rejected under 35 U.S.C. §103(a) as being unpatentable over a combination of JP '111 and GB as applied to claims 3-5, 9-11, and 38 above, and further in view of JP 53074346 (JP '346) or unpatentable over GB and JP '111 in view of CN applied to claims 3-5, 9-11, and 38, and in further view of JP '346.

Claims 3-5, 9-17, and 38 depend from independent claim 37 and claims 31-33 depend from independent claim 26. As noted above, claims 26 and 37 are submitted as being patentable over GB. The combinations of JP '111, CN, and/or JP '346 do not remedy the deficiencies of GB. Accordingly, as claims 3-5, 9-17, and 38 depend from claim 37 and claims 31-33 depend from independent claim 26 and necessarily include all the elements of their respective base claim, Applicant respectfully submits that these claims are also allowable over the cited combinations at least for the same reasons. Furthermore, each of the secondary references has been previously discussed in prior Responses to Office Actions.

Nevertheless, Applicant will address the proposed combination of references. With

respect to the combination of GB with JP '111 or CN, it appears to be suggested to apply the various beverage concentrates taught by JP '111 and CN on the tea bag of GB. Other than improper hindsight, it is unclear why one of ordinary skill in the art would be motivated to apply a coating of oolong tea, water chestnut, safflower, or any of the other disclosed beverages on a tea bag which contains tealeaves. This could possibility interfere with the colour (and to the extend disclosed flavor) improving purpose of GB. Thus, if anything, GB would actually teach against this combination.

In light of the foregoing, it is respectfully submitted that dependent claims 3-5, 9-17, 31-33 and 38 are not taught or suggested by the cited prior art, either alone or in any combination.

Conclusion

For all of the above reasons, the claim rejections are believed to have been overcome, placing claims 3-19, 26, 31-35, 37, and 38 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

No fee is believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 795-A03-012).

Respectfully submitted,

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ENCLOSURES

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